

according to the Global Harmonized System with all information required by the CPR

Printing date 07/36/2017 Teviewed on 07/36/2017

#### 1 Identification

## Product identifier

Sheet Code: 300

Trade name: Readi-CAT 2%

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#### Relevant identified uses of the substance or mixture and uses advised against

We recommend that you use this product in a manner consistent with the listed use. If your intended use is not consistent with the stated use, please contact your sales or technical service representative.

#### Application of the substance / the mixture

Radiopaque contrast media for diagnostic imaging of the gastrointestinal tract

Detailed Description: Low viscosity white colored liquid with a sweet orange and vanilla odor and no grittiness.

Route of Administration: Oral

#### Details of the supplier of the safety data sheet

#### Manufacturer/Supplier:

E-Z-EM Canada Inc.

11065 boulevard L-H. Lafontaine

Montréal, QC, Canada

H1J 2Z4

tel: (514) 353-5820

#### Further Information Obtainable from:

**B-Lands Consulting** 

www.reachteam.eu

WTC, 5 Place Robert Schuman, BP 1516

38025 Grenoble, FRANCE

Tel: +33 476 295 869 Fax: +33 476 295 870 services@reachteam.eu

#### Emergency telephone number:

EMERGENCY CONTACT: Health: 1-800-257-5181

U.S. Transport - Chemtrec: 1-800-424-9300

Intenational Transport - Chemtrec: 1-703-527-3887

#### 2 Hazard(s) identification

#### Classification of the substance or mixture

The product is not classified according to the Globally Harmonized System (GHS).

#### Label elements

GHS label elements Void

Hazard pictograms Void

Signal word Void

Hazard statements Void Additional Information:

WHMIS-symbols: Not controlled under WHIMS (Canada).

Information pertaining to particular dangers for man and environment:

Negative Effects on the Health: See also Sections 11 Negative Effects on the Environment: See also Section 12



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Results of PBT and vPvB assessment

**PBT:** Not applicable. **vPvB:** Not applicable.

## 3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture: consisting of the following components.

Active Ingredient(s):

CAS: 7727-43-7 Barium sulphate

RTECS: CR 0600000

1-<2.5%

Hazardous Components: Void

#### 4 First-aid measures

#### Description of first aid measures

General information: No special measures required.

After Skin Contact:

Remove contaminated clothing.

Immediately wash with water and soap and rinse thoroughly.

Seek medical attention if irritation (redness, itching or swelling) persists.

After Eye Contact:

Wash with running water for several minutes holding the eyelids open.

Seek medical attention if irritation (redness, itching or swelling) persists.

After Swallowing:

Do NOT induce vomiting.

Never give anything by mouth to an unconscious person.

When symptoms persist or in all cases of doubt seek medical advice.

Most important symptoms and effects, both acute and delayed See also Section 2 and 11.

#### Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Means of Specific and Immediate Treatment to Keep at the Workplace: No special measures required.

Note to physicians: Show this safety data sheet, label or product packaging.

#### **5** Fire-fighting measures

### Extinguishing media

Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

For safety reasons unsuitable extinguishing agents: Unknown.

Special hazards arising from the substance or mixture See also Section 10.

Hazardous Combustion Products: See Section 10: Hazardous decomposition products

Additional Information: Not Available

Protective Equipment:

Firefighters should wear adequate personal protective equipment with protection of respiratory tract (selfcontained breathing apparatus) (SCBA).

Wear flame and chemicals resistant clothing, boots and gloves (see Section 8).



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#### Additional information:

Move containers from fire area if safe to do so. Cool closed containers exposed to fire with water spray. Do not allow run off from fire fighting to enter drains or water courses. Dike for water control.

Evacuate personell to an upwind direction. Remove uneeded material.

#### **6** Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

Restrict access to area until completion of clean-up.

All persons dealing with the clean-up should wear the appropriate chemically protective equipment.

Refer to protective measures listed in sections 7 and 8.

#### **Environmental precautions:**

Do not allow product to enter waterways.

Do not allow material to contaminate ground water system.

#### Methods and material for containment and cleaning up:

Ventilate area of release.

Stop spill or leak at source if safely possible.

Contain and absorb spilled liquid with non-combustible, inert absorbent material (e.g. sand), then place absorbent material into a container for later disposal (see Section 13).

Notify the appropriate authorities as required.

#### Special spill response procedures:

If a spill/release in excess of the EPA reportable quantity is made into the environment, immediately notify the national response center in the United States (phone: 1-800-424-8002).

US CERCLA Reportable quantity (RQ): None reported.

#### Reference to other sections

See Section 7 for information on Safe Handling.

See Section 8 for information on Personal Protection Equipment.

See Section 13 for Disposal Information.

See Section 12 for Ecological Information.

#### 7 Handling and storage

#### Precautions for Safe Handling

Wear protective equipment appropriate to the circumstances (see Section 8)

Avoid skin and eye contact.

Provide a good ventilation / exhaustion at the workplace.

Information about fire and explosions protection: No special measures required.

#### Conditions for Safe Storage, including any Incompatibilities

### Requirements to be met by Storerooms and Receptacles:

Always keep in containers made of the same materials as the supply container.

Store in a cool, dry place in tightly closed receptacles.

Information about Storage in one Common Storage Facility: See section 10 (incompatible materials).

#### Further information about storage conditions:

Storage area should be clearly identified, clear of obstruction and accessible only to trained and authorized personnel.

Protect against physical damage.

*Specific end use(s)* No further relevant information available.

#### 8 Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.



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#### Control parameters

#### Components with limit values that require monitoring at the workplace:

(1) Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELS) from 29 CFR 1910.1000 Z-1 Table [58 FR 35340, June 30, 1993; 58 FR 40191, July 27, 1993, as amended at 61 FR 56831, Nov. 4, 1996; 62 FR 1600, Jan 10,1997; 62 FR 42018, Aug. 4,1997; 71 FR 10373, Feb. 28, 2006; 71 FR 16673, Apr. 3, 2006; 71 FR 36008, June 23, 2006.]. PELs are 8-hour time weighted averages (TWAs) unless otherwise indicated.

l	2006; /I FR 36008, June 23, 2006.]. PELs are 8-nour time weighted averages (I WAs) unless otherwise indicated.				
ľ	7727-43-7 Barium sulphate				
ľ	ACGIH (USA)	Long-term value: 10 mg/m³			
	ACGIH 2014 TLV (USA)	Long-term value: 5 mg/m <sup>3</sup>			
		Total Dust, no asbestos and <1% crystalline silica			
	CAL/OSHA PEL (USA)	Long-term value: 5*; 10** mg/m³			
		*:Respirable Fraction; **:Total Dust			
	NIOSH/GUIDE - REL (USA)	Long-term value: 5*; 10** mg/m³			
		*: Respirable Fraction; **: Total Dust			
	OSHA PEL <sub>1</sub> (USA)	Long-term value: 5*; 15** mg/m³			
		*: Respirable Fraction; **:Total Dust			
	OSHA PEL (1) (USA)	Long-term value: 5*; 15** mg/m³			
		*: Respirable Fraction; **:Total Dust			
	CAD AB OEL (Canada)	Long-term value: 10 mg/m³			
	CAD BC OEL (Canada)	Long-term value: 3*; 10** mg/m³			
		*: Respirable Fraction; **: Total Dust			
	CAD MB OEL (Canada)	Long-term value: 10 mg/m³			
	CAD ON OEL (Canada)	Long-term value: 10 mg/m³			

Additional information: The lists that were valid during the creation were used as basis.

#### Exposure controls

Additional information about Design of Technical Facilities: No further data (see Section 7).

Limitation and Environmental exposure controls: See Section 7 (Handling).

#### Personal protective equipment

#### General Protective and Hygienic Measures:

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

Wear protective equipment (PPE) appropriate to the circumstances.



Do not eat, drink, smoke while working.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

#### **Breathing Equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

#### Protection of Hands:



Wear impervious gloves if the potential exists for dermal contact.

#### Material of Gloves:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.



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Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The glove material has to be impermeable and resistant to the product/ the substance/ the mixture.

Penetration Time of Glove Material:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be

Eye Protection:



Safety goggles or glasses as appropriate for the job.

## 9 Physical and chemical properties

Information on basic physical and chemical properties

**General Information** 

Appearance:

Suspension Form: Color: White Odor: Vanilla

Odour threshold: Not determined. pH-value: Not determined. Not applicable. Melting point/Melting range: Boiling point/Boiling range: Not determined. Not determined. Flash point: Not determined.

Flammability (solid, gaseous):

Flammability limits:

Not determined. *Upper:* 

150 °C Ignition temperature:

Decomposition temperature: Not determined.

Product does not present an explosion hazard. Danger of explosion:

Flammability Limits:

Lower: Not Determined. Upper: Not Determined.

Explosion limits (vapour):

Not determined. Lower: Not determined. Upper:

Explosion limits (dust in air):

Not applicable Lower: Not applicable Upper: Oxidizing properties Not determined. Not determined. Vapour Pressure: Not determined. Density: Not determined. Relative density Vapour density Not determined. Evaporation rate: Not determined.

Solubility in / Miscibility with

Not determined. Water:



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Partition coefficient (n-octanol/water): Not determined.

Viscosity:

**Dynamic:** 600-1100 cPs **Kinematic:** Not determined.

*Water:* 0.1 %

**Other information** No further relevant information available.

#### 10 Stability and reactivity

**Reactivity:** There are not particular dangerous reactions with other substances in normal conditions of use.

**Chemical stability:** No decomposition if used and stored according to specifications.

Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

Possibility of hazardous reactions: No dangerous reactions known.

**Conditions to avoid:** No further relevant information available.

*Incompatible materials:* Reactive metals.

*Hazardous decomposition products:* Other unidentified organic compounds.

#### 11 Toxicological information

Information on toxicological effects

Acute toxicity:

Toxicological Information for Active Ingredients:

LD/LC50 values that are relevant for classification:

50-70-4 D-glucitol

Oral LD50 15900 mg/kg (rat)

7727-43-7 Barium sulphate

Oral | LD50 | > 20000 mg/kg (rat) (External SDS)

11138-66-2 Xanthan gum

Oral |LD50| > 5000 mg/kg (rat)

590-00-1 Potassium sorbate

Oral LD50 >2000 mg/kg (unknown) Dermal LD50 >2000 mg/kg (unknown)

532-32-1 Sodium Benzoate

Oral LD50 3140 mg/kg (rat) (Exernal SDS)

5989-27-5 (R)-p-mentha-1,8-diene

Oral LD50 4400 mg/kg (rat)

77-92-9 Citric Acid, Anhydrous

Oral LD50 5040 mg/kg (Mouse)

3000 mg/kg (rat) (RTEC)

Routes of Exposure: Eye contact; Skin contact; Inhalation; Ingestion.

Primary irritant effect:

Skin corrosion/Irritation: No irritating effect. Serious eye damage/Irritation: Not available.



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Respiratory or Skin Sensitisation: No reported evidences.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction):

Germ Cell Mutagenicity: No further relevant information available

Carcinogenicity: No reported evidences.

Reproductive Toxicity: Not expected to cause reproductive/teratogenic effects.

Specific Target Organ Toxicity Target organs: Eyes, skin, respiratory system, digestive system.

Aspiration Hazard: No further relevant information available

Other information (about experimental toxicology): No further relevant information available

Subacute to Chronic Toxicity: No further relevant information available

Carcinogenic categories

IARC (International Agency for Research on Cancer)	
5989-27-5 (R)-p-mentha-1,8-diene	3
6155-57-3 Saccharin Sodium dihydrate	Yes: Carc. 3
NTP (National Toxicology Program)	
6155-57-3 Saccharin Sodium dihydrate	YES
Any Eventual Delayed Effect after Prolonged Exposure: Not completely tested from a toxicological	point of view.

#### Any Eventual Delayed Effect after 1 rolonged Exposure. 100 completely tested from a toxicological point of view

<b>12 Eco</b>	logical	linf	orma	tion
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Toxicity				
Aquatic toxicity:				
7727-43-7 Barium sulphate				
EC50/48h 32 mg/L (Daphnia Magna)				
11138-66-2 Xanthan gum				
LC50/48h 980 mg/L (Daphnia Magna)				
LC50/96h > 50000 ppm (Mysid Shrimp) (Suspended Particulate (2 lb./bbl of Xanthan Gum))				
490 mg/L (Rainbow Trout)				
532-32-1 Sodium Benzoate				
ECO 1000 mg/L (Bacteria) (Exernal SDS)				
EC50/48h > 100 mg/L (Daphnia) (Exernal SDS)				
IC50/72h > 10 mg/L (Algae) (Exernal SDS)				
LC50 460 mg/L (Leuciscus Idus) (ECOTOX Database)				
77-92-9 Citric Acid, Anhydrous				
EC5/16h  > 10000 mg/L (Pseudomonas Putida) (Literature)(Max. Permissible Toxic Concentration)				
EC5/72h 485 mg/L (Echinodontium Sulcatum) (Literature)				
EC50/72h ca. 120 mg/L (Daphnia Magna) (IUCLID)				
IC5/7d 640 mg/L (Scenedesmus Quadricauda) (Literature)(Max. Permissible Toxic Concentration)				
IC5/8d 80 mg/L (Microcystis Aeruginosa) (Literature)(Max. Permissible Toxic Concentration)				
LC50 440-706 mg/L (Fish)				

Persistence and degradability No further relevant information available.

Bioaccumulative potential No further relevant information available.

*Mobility in soil:* No further relevant information available.

LC50/96h 440 - 760 mg/L (Leuciscus Idus) (IUCLID)



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#### Additional ecological information:

The product should not be allowed to enter drains or water courses, or be deposited where it can affect ground or surface waters

Use according to the good working pactice. Avoid transfer into the environment.

General notes: Generally not hazardous for water

Results of PBT and vPvB assessment

**PBT:** Not applicable. **vPvB:** Not applicable.

Other adverse effects No further relevant information available.

#### 13 Disposal considerations

#### Waste treatment methods:

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Recommendation:** Reutilise if possible or contact a waste processors for recycling or safe disposal.

#### Waste disposal key:

If this product, as supplied, becomes a waste in the United States, it may meet the criteria of a hazardous waste as defined under RCRA, Title 40 CFR 261. It is the responsibility of the waste generator to determine the proper waste identification and disposal method. For disposal of unused or waste material, check with local, state and federal environmental agencies.

#### Uncleaned packagings:

#### Recommendation:

The containers and packing materials contaminated with hazardous substances or mixtures, have the same treatment products.

**Recommended cleansing agent:** Not Available

#### 14 Transport information

**UN-Number** 

ADR, ADN, IMDG, IATA Void

UN proper shipping name

ADR, ADN, IMDG, IATA Void

Transport hazard class(es)

ADR, ADN, IMDG, IATA

*Class* Void

Packing group

ADR, IMDG, IATA Void

Environmental hazards:

Marine pollutant: No

Special precautions for user Not applicable.

Transport in bulk according to Annex II of

MARPOL73/78 and the IBC Code Not applicable.



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Printing date 05/14/2015 Version 2 Reviewed on 05/14/2015 Trade name: Readi-CAT 2% UN "Model Regulation": 15 Regulatory information Safety, health and environmental regulations/legislation specific for the substance or mixture This safety data sheet complies with the requirements of Global Harmonized System, including also all information required by the CPR Sara Section 355 (extremely hazardous substances): None of the ingredients is listed. Section 313 (Specific toxic chemical listings): None of the ingredients is listed. TSCA (Toxic Substances Control Act): 50-70-4 D-glucitol 7727-43-7 Barium sulphate 11138-66-2 | Xanthan gum 590-00-1 Potassium sorbate 63148-62-9 Polydimethylsiloxane 532-32-1 Sodium Benzoate 5989-27-5 (R)-p-mentha-1,8-diene 7732-18-5 Water USP 77-92-9 Citric Acid, Anhydrous 9005-71-4 Polyethlyene glycol sorbitan tristearate 9004-67-5 Methocel 63231-67-4 Silica gel 123-35-3 7-methyl-3-methyleneocta-1,6-diene 5392-40-5 3,7-DIMETHYL-2,6-OCTADIENAL (CIS/TRANS ISOMERS) **Proposition 65** Chemicals known to cause cancer: None of the ingredients is listed. Chemicals known to cause reproductive toxicity for females: None of the ingredients is listed. Chemicals known to cause reproductive toxicity for males: None of the ingredients is listed. Chemicals known to cause developmental toxicity: None of the ingredients is listed. Carcinogenic categories EPA (Environmental Protection Agency) None of the ingredients is listed. TLV (Threshold Limit Value established by ACGIH) None of the ingredients is listed. NIOSH-Ca (National Institute for Occupational Safety and Health) None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.



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GHS label elements Void Hazard pictograms Void Signal word Void Hazard statements Void

Other regulations, limitations and prohibitive regulations

#### WHMIS-symbols:

This product has been classified according to the hazard criteria of the CPR and this SDS contains all of the information required by the CPR.

Not controlled under WHIMS (Canada).

#### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

#### Training hints

All persons handling this product should be informed on the existence of the hazard, on any possible risk they might be subjected to and about all required protective measures to prevent such a damage or to reduce the exposition.

#### Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

WHMIS: Workplace Hazardous Materials Information System (Canada)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent